UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/332,659	06/14/1999	FREDERIC ZENHAUSERN	4467-102US	3190

7590 06/16/2003

CHARLES J BRUMLIK ESQ
MATHEWS COLLINS SHEPHERD & GOULD PA
SUITE 306
100 THANET CIRCLE
PRINCETON, NJ 08540

EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/332,659	Zenhausern
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 27, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4-18, 25, 26, 36, 37, 40-42, and 44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4-18, 25, 26, 36, 37, 40-42, and 44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Specification

1. Claims 1, 4-17, 37, 41, and 44 have been amended. Claims 2, 3, 19, 21, 35, and 43 have been canceled without prejudice towards further prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4-18, 25, 26, 36, 37, 40-42, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected over the recitation of the phrase, "can be detected" on line 6. The phrase "can be detected" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 4, 5-6, 8, 10-18, 25, 26, 37, and 40 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Ghahramani et al. (U.S. Patent 6,259,373 B1) (July 10, 2001) further in view of Kriz (U.S. Patent 6,214,206 B1) (April 10, 2001).

Nova et al teach a method for monitoring information in a solid medium (Abstract), the medium comprising the steps of:

a) screening the medium with a screening means comprising a n number of sensing probes, where n is an integer of at least one so that more than one physical, chemical, or physico-chemical change which defines the information is detected by the probe to produce at least one signal output (Column 5, line 51 to Column 6, line 30, Column 25, line 66 to Column 26, line 4 and Column 79, lines 23 to column 89, line 30);

b) transferring the signal output to a signal processing means responsive to differences in electromagnetic properties of the signal for generating a final output (Column 6, lines 52-56, Column 12, lines 20-37 and Column 90, lines 27-54, Figure 7);

c) receiving the final output into a pattern recognition means sufficient to generate a measurement pattern of the information being operable to define a set of class boundaries (Column 7, line 64 to Column 8, line 18, Figures 24 and 31); and

d) sorting the information in accordance with the class boundaries representative of the presence and preferably quantitative amounts of biomolecule in the medium (Figure 31, Column 79, line 50 to Column 80, line 16 and Column 90, line 55 to column 91, line 53).

Nova et al teach a method wherein the n number of sensing probes is a multiple sensor array (Abstract and Column 87, line 31 to Column 89, line 31 and Column 7, lines 35-49).

Nova et al teach a method wherein the sensing probe comprises at least one conductive polymer sensor (Column 68, lines 28-38).

Nova et al teach a method wherein the sensing probe has a coating (Column 68, lines 28-38).

Nova et al teach a method wherein the sensing probe is an optical sensing probe (Abstract and Column 63, lines 30-62).

Nova et al teach a method wherein the sensing probe is an optical fiber (Column 63, line 63 to Column 64, line 18).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in the concentration of the biomolecule (Column 79, line 50 to Column 80, line 16).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a secondary product of the biomolecule (Column 91, line 55 to Column 92, line 40).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a radiative property of the electromagnetic spectrum of the biomolecule (Column 6, lines 52-56, Column 12, lines 20-37 and Column 90, lines 27-54, Figure 7).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a non-radiative property of the electromagnetic spectrum of the biomolecule (Column 77, line 63 to Column 78, line 63).

Nova et al teach a method wherein at least part of the information detected by the probe is changes in a non-radiative property of the electromagnetic spectrum of a secondary product of the biomolecule (Column 91, line 55 to Column 92, line 40).

Nova et al teach a method wherein the medium comprises at least one of organic or inorganic solvent (Example 1).

Nova et al teach a method wherein the signal processing means comprises a frequency analyzer (Figure 24 and Column 81, lines 19-42).

Nova et al teach a method wherein the optical probe is an apertureless or apertured probe (Figure 8 and Column 55, line 44 to Column 56, line 23).

Nova et al teach a method wherein the medium is a mixture of amplification products and monitoring step monitors an amplification reaction (Column 13, lines 23-46).

Nova et al. do not teach a method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase.

Ghahramani et al. teach a method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase.(Column 24, lines 37-55).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. since Ghahramani et al. state, "The gas sensors must fulfill many exploitation requirements: the most important parameters are: sensitivity, selectivity, reading reproducibility, stability during the operation, quick response, small size safety operation, low power consumption, ~15 mW, and low cost (Column 24, lines 43-48)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. to improve the gas sensor probes. An ordinary practitioner would have been motivated to combine and substitute the method wherein the medium is a gas or vapor, and wherein the sensing probe comprises at least one of a metal oxide gas sensor used in gas or vapor phase. of Ghahramani et al. into the method of monitoring information of Nova et al. in order to achieve the express advantages noted by Ghahramani et al., of an invention that provides sensitivity, selectivity, reading reproducibility, stability during the operation, quick response, small size safety operation, low power consumption, ~15 mW, and low cost.

Nova et al. in view of Ghahramani et al. do not teach a method of screening means comprising a multisensor array.

Kriz teaches a method of screening means comprising a multisensor array (Abstract, Column 4, lines 10-23 and Table 1 and Column 2, lines 47-62), which can detect the quality and quantity of enzymes and nucleic acids.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method of screening means comprising a multisensor array, which can detect the quality and quantity of enzymes and nucleic acids of Kriz into the method of monitoring information of Nova et al in view of Ghahramani et al. since Kriz states, "Thus the analyses would be more rapid and the times of response shorter, and in addition it will be possible to control the risk of contamination and deactivation of the recognition element. The reason for this is that the measurement process is dynamic, which allows initial changes to be put in relation to the concentration of analyte in the sample solution, and that there is no need for the recognition element to be regenerated. The invention also allows sequential detection of several analytes with one and the same transducer means. It also permits differential measurements with and without recognition elements in order to reduce the effect of interfering compounds. All these new features and advantages will be of great economic importance and will give opportunities for new applications in the industrial, medical and research fields (Column 2, lines 51-65)." An ordinary artisan would have combined and substituted a method of screening

means comprising a multisensor array, which can detect the quality and quantity of enzymes and nucleic acids of Kriz into the method of monitoring information of Nova et al in view of Ghahramani et al. to improve the specific detection of nucleic acid and enzymatic products. An ordinary practitioner would have been motivated to combine and substitute a method of screening means comprising a multisensor array, which can detect the quality and quantity of enzymes and nucleic acids of Kriz into the method of monitoring information of Nova et al in view of Ghahramani et al. in order to achieve the express advantages noted by Kriz, of an invention that allows sequential detection of several analytes with one and the same transducer means and also permits differential measurements with and without recognition elements in order to reduce the effect of interfering compounds and which provides new features and advantages that are of great economic importance and give opportunities for new applications in the industrial, medical and research fields.

6. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Ghahramani et al. (U.S. Patent 6,259,373 B1) (July 10, 2001) further in view of Kriz (U.S. Patent 6,214,206 B1) (April 10, 2001) further in view of Takakura et al. (US 6,462,185 B1) (October 8, 2002) .

Nova et al. in view of Ghahramani et al. further in view of Kriz teach the method of claims 1, 4, 5-6, 8, 10-18, 25, 26, 37, and 40 as described above.

Nova et al. in view of Ghahramani et al. further in view of Kriz do not teach the method, wherein the polymerase is a Taq mediated PCR.

Takakura et al teach the method, wherein the polymerase is a Taq mediated PCR (Column 5, lines 49-55).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the polymerase is a Taq mediated PCR of Takakura et al. into the method of monitoring information of Nova et al. in view of Ghahramani et al. further in view of Kriz since Takakura et al. states, "Also, the substitution, deletion, addition or insertion of specific nucleotide(s) may be conducted by the site-directed mutagenesis with the use of the PCR method or the random nucleotide substitution technique by taking advantage of the low fidelity of Taq DNA polymerase (Column 5, lines 49-55)." An ordinary practitioner would have been motivated to combine and substitute a method, wherein the polymerase is a Taq mediated PCR of Takakura et al. into the method of monitoring information of Nova et al. in view of Ghahramani et al. further in view of Kriz in order to achieve the express advantages noted by Takakura et al., of an invention by which the substitution, deletion, addition or insertion of specific nucleotide(s) may be conducted by the site-directed mutagenesis with the use of the PCR method or the random nucleotide substitution technique by taking advantage of the low fidelity of Taq DNA polymerase.

7. Claims 7, and 9 are rejected under 35 U.S.C. 103(a) over Nova et al. (U.S. Patent 6,100,026) (August 8, 2000) in view of Ghahramani et al. (U.S. Patent 6,259,373 B1) (July 10, 2001) further in view of Kriz (U.S. Patent 6,214,206 B1) (April 10, 2001). further in view of Ashe et al. (U.S. Patent 5,699,270) (December 16,1997).

Nova et al. in view of Ghahramani et al. further in view of Kriz teach the method of claims 1, 4, 5-6, 8, 10-18, 25, 26, 37, and 40 as described above.

Nova et al. in view of Ghahramani et al. further in view of Kriz do not teach a method wherein the sensing probe is a resonant micromechanical device mass spectrometer.

Ashe et al. teach a method wherein the sensing probe is a resonant micromechanical device mass spectrometer (Abstract and Claim 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Ghahramani et al. further in view of Kriz since, since Ash et al. state, "Coefficients provided by this model are mathematically combined with the suitably treated mass spectral data from samples with unknown desired properties to: a) predict desired properties, b)assess the suitability of the model for such predictions, and c) diagnose the stability and general correctness of the process that yielded the mass spectral data (Column 7, lines 4-12)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Ghahramani et al. further in view of Kriz to improve the method of monitoring information of a biomolecule. An ordinary practitioner would have been motivated to combine

and substitute the method wherein the multivariate analysis is principal component analysis, deterministic finite-state automata, partial least squares and trained or untrained of Ashe et al. into the method of monitoring information of Nova et al. in view of Ghahramani et al. further in view of Kriz in order to achieve the express advantages noted by Ashe et al., of an invention that provides coefficients which are mathematically combined with the suitably treated mass spectral data from samples with unknown desired properties to: a) predict desired properties, b)assess the suitability of the model for such predictions, and c) diagnose the stability and general correctness of the process that yielded the mass spectral data.

Allowable Subject Matter

8. No prior art rejections have been made with regard to claims 36, 37, and 41.

Response to Amendment

9. In response to amendment, previous 103(a) rejections are hereby withdrawn. However, three new 103 (a) rejections along with a new 112 (second paragraph) rejections are hereby included.

Response to Arguments

10. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. Any inquiry of a general nature or relating to the status of this application should be directed tithe Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted

to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazed OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

Art Unit 1634

June 11, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600